

REMARKS

Reconsideration of this application and allowance of the amended claims is respectfully requested.

Claim 1 has been amended by inclusion of limitations of claims 7-8 and 12. Claim 16 has been amended by inclusion of limitations of claim 17. Claim 26 has been amended by inclusion of limitations of claims 29-32.

Thus, the amended claims are believed to be clearly supported by the original disclosure.

The examiner has rejected all claims as unpatentable over Hayzelden et al. US 2002/0165534 A1 in view of Hampton U.S. Patent No. 4,940,062.

It should be noted that those skilled in the art, having Hayzelden and Hampton before them, would be led away from making any combination of the two references because Hayzelden discloses an ablation catheter for heat ablation of portions of the heart and the like, which is a type of catheter that never uses a balloon. Thus, the combination of the two references cited by the examiner of a catheter that never uses a balloon, and a balloon catheter, is improper.

Furthermore, referring to claim 1, the material added by amendment calls for an attachment member (22) in the form of a rounded bead which contacts the distal end of the helical coil and defines a curved surface at the distal end of the coil.

Hayzelden does not disclose a helical coil as claimed. Instead Hayzelden discloses "three layers 80, 82, and 84...bonded together, thus creating a flexible tube with the braided stainless steel ribbon of the middle layer 82..." Hayzelden, paragraph 0032. This braided stainless steel ribbon 82 can be plainly seen to terminate well short of anything that might qualify as an "attachment member" so that, in addition to it not

being a helical coil, there is no “attachment member engaging the distal end of the helical coil” (claim 1, paragraph 6) disclosed in Hayzelden.

Furthermore, claim 1 carries the limitation “the deflection ribbon engages the rounded bead at a location offset from the center of the curved surface of the rounded bead; and the distal end of the retaining ribbon engages the rounded bead at a location offset from the center of the curved surface of the rounded bead...”

Thus, claim 1 calls for a pair of flat ribbons, namely reference numerals 34, 24, shown for example in Fig. 4, engaging rounded bead 22, which two ribbons 34, 24 preferably are joined together in a single unitary element as called for in claim 11. Because of this, the tip of the steerable balloon catheter of this invention is capable of being bent in two opposite directions by either pushing or pulling deflection member 20 from the proximal end of the catheter.

To the contrary, where Hayzelden has a flat ribbon 124, it is positioned centrally along the axis of the catheter and is used for return of the distal-end region 24 back to flat, straight shape. See paragraph 0043. It is not used for bending of the tip, which bending is controlled in Hayzelden by the pair of steering tendons 54, 56. See paragraph 0031. It can also be seen that steering tendons 54, 56 are not in flat ribbon form, see Fig. 6. By the present invention, a flat ribbon replaces a pair of steering tendons 54, 56 and the flat ribbon 124 found in Hayzelden, for a significant simplification of parts, while still providing stability of shape and bendability at the tip, as controlled from the proximal end of the catheter.

Hampton also fails to disclose the new limitations of claim 1, in which the respective ribbons 24, 25 of Hampton fail to “form a generally U-shaped configuration . .

.” Rather, the two flattened portions 24, 25 of Hampton simply abut directly into the rounded bead attachment member in a manner contrary to that disclosed in this application.

Thus, it is submitted that claim 1 and its dependent claims are patentable.

Turning to independent claim 16, the limitation has been added “said retaining member being pre-shaped into an arcuate configuration to thereby cause the flexible helical coil to be normally biased into a curved shape.”

Turning to Hayzelden, it can be seen from paragraph [0043 and 0044] that the purpose of flat ribbon 124 is “...Such material permits the flat ribbon 124 to deflect with the distal-end region of the sheath 22 yet the shape-memory aspect of the flat ribbon tends to return the flat ribbon, and also the catheter distal end, to the straight, or non-deflected, shape...” (emphasis added). That, and torsional strength, is the purpose of Hayzelden’s flat ribbon 124. It is very clear that Hayzelden does not teach pre-shaping of the catheter tip into an arcuate configuration but instead teaches the contrary.

Turning to Hampton, Fig. 12 does show the catheter with a curved tip, while the other drawings show the tip as flat. However, referring to Fig. 12 in the specification, at column 6, line 10 *et seq.* of Hampton, it is stated: “The flattened section 24 of core 11 is shown manually bent to a desired shape.

This is dynamic bending, manually caused during use by manipulation at the proximal end of the catheter, as also indicated by column 5, lines 40-45 relating to a previous embodiment: “Core element 11 is pulled axially in the proximal direction causing the expanded coil section 16 to be compressed. Reference member 18 is thrust distally toward plug 22, but because it is secured thereto will cause the tip to

deflect as shown by arrow 40.” These same reference numerals are used in Fig. 12, and thus the functioning described applies equally to the Fig. 12 embodiment. There is no teaching of pre-shaping of a retaining member into an arcuate configuration to cause the flexible helical coil to be normally biased into a curved shape, as called for in independent claim 16 and its dependent claims.

The attention of the Examiner is also directed to claim 22, dependent upon claim 16, wherein the deflection member and the retaining member are required to be joined to each other within the attachment member, as clearly shown in the drawings of this application.

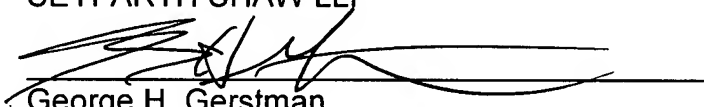
Turning to claim 26, as previously discussed, the steerable balloon catheter of this invention requires that the deflection ribbon and the retaining ribbon are joined to each other within the rounded bead. This is not disclosed in Hampton, nor is it shown by the respective pair of steering tendons 54, 56 of Hayzelden, which do not constitute joined ribbons, nor is it shown by the ribbon 124 of Hayzelden, centrally positioned rather than laterally positioned as are the ribbons called for in claim 26, and not used for steering as are the ribbons of claim 26.

Thus, it is submitted that claim 26 and its dependent claims are patentable.

In view of the above, allowance of the claims is respectfully requested.

Respectfully submitted,

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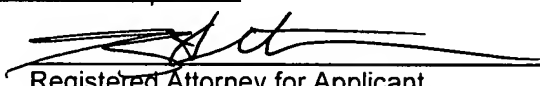


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Date: June 21, 2007